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Treatment of genital herpes with chlorous acid releasing gel

In an open study, a chlorous acid releasing gel (Allay gel, Alcide Corporation), with *in vitro* activity against herpes simplex virus was shown to have efficacy in the treatment of initial genital herpes.¹

We have conducted a double blind, multiple cross-over randomised trial to assess the efficacy of this preparation when compared with a placebo in the treatment of recurrent genital herpes. The study was conducted at the Praed Street Clinic, St Mary's Hospital, and prior approval of the district ethics committee was obtained.

We studied 100 patients (56 female, 44 male) during one to four episodes each. Patients were excluded if they were pregnant or lactating, known to be HIV positive, or had used antiviral drugs or immune modulators within 14 days of admission to the study. All patients had had at least one virologically confirmed episode of genital herpes before admission to the study and other concurrent infections were excluded by conventional techniques on enrolment.

Each patient was fully counselled and gave written informed consent. The technique of administration, which involved the mixing of the contents of two sachets before application to the lesions, was explained and the patients asked to apply the treatment twice daily for seven days. Each patient was asked to keep a record of symptoms and an assessment was made by the investigators on days 1, 2, 3-5 and 8. At the completion of each episode, the patient

was supplied with treatment for the next episode and asked to start therapy only if this could be achieved within 6 hours of the onset of symptoms. Treatment for the first two episodes and the second two episodes were randomised to active or placebo preparation separately so that each patient received active drug for either the first or the second episode.

Only 49 patients completed two or more episodes. No significant difference in time to healing or duration of viral shedding was noted when the first two episodes were compared in these patients. Similarly when all placebo treated episodes were compared with all Allay gel treated episodes there was no significant difference (table) in the healing time or duration of viral shedding. However, in male patients the mean duration of viral shedding was shorter in patients treated with the active preparation although this did not reach statistical significance. For most parameters, the placebo preparation appeared to perform marginally better than the active preparation.

Patients treated with the active preparation noted more adverse events (13 vs 2) and in three patients bleaching of the pubic hair was noted. The treatment was unpopular with many patients, which may have accounted for the poor recruitment and high drop-out rate in this study.

These data demonstrate that Allay gel is unlikely to be of benefit in the management of recurrent genital herpes, at least in its present format. This contrasts with the results of a previous open study in which benefit was suggested in the management of initial genital herpes. One possible explanation may be that in initial genital herpes viral shedding may be prolonged and the anti-viral effect of the preparation useful. In recurrent herpes, when viral shedding may only be transient, the application of an acidic gel may delay healing.

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Table Time to healing and duration of viral shedding in patients treated with Allay gel or placebo

Treatment	Time to healing (days, (SD))		Duration of viral shedding (days, (SD))	
	Males (44)	Females (56)	Males (44)	Females (56)
Allay gel	6.12 (2.47)	5.65 (2.25)	1.85 (1.25)	2.53 (1.77)
Placebo	5.47 (2.59)	5.23 (2.85)	3.50 (2.67)	2.87 (2.13)